Applicant

Medsep Corporation
A Subsidiary of Pall Corporation
1630 Industrial Park Street
Covina, CA 91722

Primary Contact

Edward J. Nelson
Medsep Corporation
Director, Regulatory and Scientific Affairs
1630 Industrial Park Street
Covina, CA 91722

Telephone Number: 626-915-8227
Fax Number: 626-915-8253

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Device Name

Proprietary Name: Pall BDS Sample Set

Common Name: Bacteria Detection System Sample Set

Classification Name: System, detection, bacterial, for platelet transfusion products

Classification Code: MZC
Immunology (medical specialty)

Predicate Device

Traditional culture methodology and BacT/Alert® Culture Bottles

Description of Device

The Pall BDS Sample Bag Set is a sterile, stand-alone, disposable device to be sterilely docked to a platelet storage bag for transfer of a test sample in a closed system. The device includes tubing, a filter, a sampling site, and a culture bag containing a bacterial growth-enhancing agent. Proliferation of bacteria in the test sample results in consumption of oxygen, which can be used as a surrogate marker for bacterial growth. The proposed device permits detection of bacterial growth in the test sample when used in conjunction with an oxygen gas analyzer.

Intended Use

Pall BDS Sample Sets are intended to be used with the Pall BDS Oxygen Analyzer in qualitative procedures for the recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria) for quality control testing of leukocyte reduced apheresis or whole blood derived platelet units.

Comparison to Predicate Device

Comparisons were made to traditional culture methodology and to BacT/Alert® Culture Bottles. The Pall BDS Sample Set is similar to the predicate devices in intended use, and they are *in vitro* diagnostic test systems which are based on microbial growth. The BDS Sample Set is also similar to BacT/Alert® Culture Bottles in that both contain a microbial growth-enhancing reagent, both rely on changes in a respiration gas as a surrogate marker for bacterial growth, and both are used in conjunction with other instruments for qualitative detection of microbial growth via the surrogate markers. The BDS Sample Set is different from the predicate devices in that the latter contain culture media whereas the BDS Sample Set utilizes transferred plasma and the contained growth-enhancing reagent as the growth medium. The BDS Sample Set uses consumption of oxygen as the surrogate marker, whereas BacT/Alert® Culture Bottles use the production of carbon dioxide.

Non-Clinical tests submitted

Testing was performed to establish the performance characteristics of the BDS Sample Set and comparisons to traditional culture methodology were included.

Conclusion

The information and data contained herein demonstrate the BDS Sample Set performs as intended and is substantially equivalent to traditional culture methodology and BacT/Alert® Culture Bottles based on similarity of intended use and performance.